ARTICLE 2. NEWBORN AND INFANT SCREENING

R9-13-201. Definitions

In this Article, unless otherwise specified:

1. No change (*"Abnormal result" means an outcome that deviates from the range of values established by the Department for an analysis performed as part of a bloodspot test, or for a hearing test.*
2. No change (*"Admitted" means the same as in A.A.C. R9-10-201.*
3. No change (*"AHCCCS" means the Arizona Health Care Cost Containment System.*
4. No change (*"Argininosuccinic acidemia" means a congenital disorder characterized by an inability to metabolize the amino acid argininosuccinic acid due to defective argininosuccinate lyase activity.*
5. No change (*"Audiological equipment" means instruments used to measure a physiological response to determine the presence, type, or degree of hearing loss.*
6. "Audiologist" means ~~an individual licensed under A.R.S. Title 36, Chapter 17~~ the same as in A.R.S. § 36-1901.
7. No change (*"Beta-ketothiolase deficiency" means a congenital disorder characterized by an inability to metabolize 2-methyl-acetoacetyl-CoA due to defective mitochondrial acetoacetyl-CoA thiolase activity.*
8. No change (*"Biotinidase deficiency" means a congenital disorder characterized by defective biotinidase activity that causes abnormal biotin metabolism.*
9. No change (*"Birth center" means a health care facility that is not a hospital and is organized for the sole purpose of delivering newborns.*
10. No change (*"Blood sample" means capillary or venous blood, but not cord blood, applied to the filter paper of a specimen collection kit.*
11. "Bloodspot test" means multiple laboratory analyses performed on a blood sample to detect the presence of the congenital disorders ~~listed~~ specified in R9-13-202(A), R9-13-202(B), or R9-13-202(C).
12. No change (*"Carnitine uptake defect" means a congenital disorder characterized by a decrease in the amount of free carnitine due to defective sodium ion-dependent carnitine transporter OCTN2 activity.*
13. No change (*"Citrullinemia" means a congenital disorder characterized by an inability to convert the amino acid citrulline and aspartic acid into argininosuccinic acid due to defective argininosuccinate synthetase activity.*

14. No change (*"Classic galactosemia" means a congenital disorder characterized by abnormal galactose metabolism due to defective galactose-1-phosphate uridyltranferase activity.*
15. No change (*"Congenital adrenal hyperplasia" means a congenital disorder characterized by decreased cortisol production and increased androgen production due to defective 21-hydroxylase activity.*
16. No change (*"Congenital disorder" means an abnormal condition present at birth, as a result of heredity or environmental factors, that impairs normal physiological functioning of a human body.*
17. No change (*"Congenital hypothyroidism" means a congenital disorder characterized by deficient thyroid hormone production.*
18. No change (*"Cystic fibrosis" means a congenital disorder caused by defective functioning of a transmembrane regulator protein and characterized by damage to and dysfunction of various organs, such as the lungs, pancreas, and reproductive organs.*
19. No change (*"Department" means the Arizona Department of Health Services.*
20. "Diagnostic hearing test" means a type of hearing test performed by an audiologist or a physician to determine whether a newborn or infant has a hearing loss and, if so, the type and degree of hearing loss.

~~20.~~21. No change (*"Discharge" means the termination of inpatient services to a newborn or infant.*

~~21.~~22. No change (*"Disorder" means a disease or medical condition that may be identified by a laboratory analysis.*

~~22.~~23. No change (*"Document" means to establish and maintain information in written, photographic, electronic, or other permanent form.*

~~23.~~24. No change (*"Educational materials" means printed or electronic information provided by the Department, explaining newborn and infant screening, any of the congenital disorders listed in R9-13-202, or hearing loss.*

~~24.~~25. No change (*"Electronic" means the same as in A.R.S. § 44-7002.*

~~25.~~26. No change (*"First specimen" means the initial specimen that is collected from a newborn who is less than five days of age and sent to the screening laboratory for testing and recording of demographic information.*

~~26.~~27. No change (*"Glutaric acidemia type I" means a congenital disorder characterized by an accumulation of glutaric acid due to defective glutaryl-CoA dehydrogenase activity.*

~~27.~~28. No change (*"Guardian" means an individual appointed by a court under A.R.S. Title 14, Chapter 5, Article 2.*

~~28.~~29. No change (*"Health care facility" means a health care institution defined in A.R.S. § 36-401 where obstetrical care or newborn care is provided.*

~~29.~~30. No change (*"Health care provider" means a physician, physician assistant, registered nurse practitioner, or midwife.*

~~30.~~31. No change (*"Health-related services" means the same as in A.R.S. § 36-401.*

~~31.~~32. No change (*"Hearing test" means an evaluation of both ears of a newborn or infant, using audiological equipment, for the presence, type, or degree of hearing loss.*

~~32.~~33. No change (*"Hemoglobin S/Beta-thalassemia" means a sickle cell disease in which an individual has one sickle cell gene and one gene for beta thalassemia, another inherited hemoglobinopathy.*

~~33.~~34. No change (*"Hemoglobin S/C disease" means a sickle cell disease in which an individual has one sickle cell gene and one gene for another inherited hemoglobinopathy called hemoglobin C.*

~~34.~~35. No change (*"Hemoglobinopathy" means a congenital disorder characterized by abnormal production, structure, or functioning of hemoglobin.*

~~35.~~36. No change (*"Home birth" means delivery of a newborn, outside a health care facility, when the newborn is not hospitalized within 72 hours of delivery.*

~~36.~~37. No change (*"Homocystinuria" means a congenital disorder characterized by abnormal methionine and homocysteine metabolism due to defective cystathione-ß-synthase activity.*

~~37.~~38. No change (*"Hospital" means the same as in A.A.C. R9-10-201.*

~~38.~~39. No change (*"Hospital services" means the same as in A.A.C. R9-10-201.*

~~39.~~40. No change (*"3-Hydroxy-3-methylglutaric aciduria" means a congenital disorder characterized by the accumulation of 3-hydroxy-3-methylglutaric acid due to a defective 3-hydroxy-3-methylglutaryl-CoA lyase activity.*

~~40.~~41. No change (*"Identification code" means a unique set of numbers or letters, or a unique set of both numbers and letters, assigned by the Department to a health care facility, a health care provider, an audiologist, or another person submitting specimen collection kits to the screening laboratory or hearing test results to the Department.*

~~41.~~42. No change (*"Infant" means the same as in A.R.S. § 36-694.*

~~42.~~43. No change (*"Inpatient" means an individual who:*

a. No change (*Is admitted to a hospital,*

b. No change (*Receives hospital services for 24 consecutive hours, or*

c. No change (*Is admitted to a birth center.*

~~43.~~44. No change (*"Inpatient services" means medical services, nursing services, or other health-related services provided to an inpatient in a health care facility.*

~~44.~~45. No change (*"Isovaleric acidemia" means a congenital disorder characterized by an accumulation of isovaleric acid due to defective isovaleryl-CoA dehydrogenase activity.*

~~45.~~46. No change (*"Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 12 to 16 carbon atoms in length due to defective long-chain 3-hydroxy acyl-CoA dehydrogenase activity.*

~~46.~~47. No change (*"Maple syrup urine disease" means a congenital disorder of branched chain amino acid metabolism due to defective branched chain-keto acid dehydrogenase activity.*

~~47.~~48. No change (*"Medical services" means the same as in A.R.S. § 36-401.*

~~48.~~49. No change (*"Medium chain acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 6 to 10 carbon atoms in length due to defective medium-chain acyl-CoA dehydrogenase activity.*

~~49.~~50. No change (*"3-Methylcrotonyl-CoA carboxylase deficiency" means a congenital disorder characterized by an accumulation of 3-methylcrotonyl-glycine due to defective 3-methylcrotonyl-CoA carboxylase activity.*

~~50.~~51. No change (*"Methylmalonic acidemia (Cbl A,B)" means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective activity of methylmalonyl-CoA racemase or adenosylcobalamin synthetase.*

~~51.~~52. No change (*"Methylmalonic acidemia (mutase deficiency)" means a congenital disorder characterized by an accumulation of methylmalonic acid due to defective methylmalonyl-CoA mutase activity.*

~~52.~~53. No change (*"Midwife" means an individual licensed under A.R.S. Title 36, Chapter 6, Article 7, or certified under A.R.S. Title 32, Chapter 15.*

~~53.~~54. No change (*"Multiple carboxylase deficiency" means a congenital disorder characterized by an inability to transport or metabolize biotin that leads to defective activity of propionyl-CoA carboxylase, beta-methylcrotonyl-CoA carboxylase, and pyruvate carboxylase.*

~~54.~~55. No change (*"Newborn" means the same as in A.R.S. § 36-694.*

~~55.~~56. No change (*"Newborn care" means medical services, nursing services, and health-related services provided to a newborn.*

~~56.~~57. No change (*"Nursing services" means the same as in A.R.S. § 36-401.*

~~57.~~58. No change (*"Obstetrical care" means medical services, nursing services, and health-related services provided to a woman throughout her pregnancy, labor, delivery, and postpartum.*

~~58.~~59. No change (*"Organ" means a somewhat independent part of a human body, such as a salivary gland, kidney, or pancreas, which performs a specific function.*

~~59.~~60. No change (*"Parent" means a natural, adoptive, or custodial mother or father of a newborn or infant.*

~~60.~~61. No change (*"Person" means the state, a municipality, district, or other political subdivision, a cooperative, institution, corporation, company, firm, partnership, individual, or other legal entity.*

~~61.~~62. No change (*"Phenylketonuria" means a congenital disorder characterized by abnormal phenylalanine metabolism due to defective phenylalanine hydroxylase activity.*

~~62.~~63. No change (*"Physician" means an individual licensed under A.R.S. Title 32, Chapters 13, 14, 17, or 29.*

~~63.~~64. No change (*"Physician assistant" means an individual licensed under A.R.S. Title 32, Chapter 25.*

~~64.~~65. No change (*"Propionic acidemia" means a congenital disorder characterized by an accumulation of glycine and 3-hydroxypropionic acid due to defective propionyl-CoA carboxylase activity.*

~~65.~~66. No change (*"Registered nurse practitioner" means the same as in A.R.S. § 32-1601.*

~~66. "Screening laboratory" means an entity contracted with the Department under A.R.S. § 36-694(I) to perform the bloodspot test.~~

67. "Screening laboratory" means the Arizona State Laboratory, the part of the Department that:

a. Is authorized by A.R.S. Title 36, Chapter 2, Article 2, and A.R.S. § 36-132(A)(11); and

b. Performs serological, microbiological, entomological, and chemical analyses.

~~67.~~68. No change (*"Second specimen" means a specimen that is sent to the screening laboratory for testing and recording of demographic information, after being collected:*

a. No change (*From a newborn after a first specimen; or*

b. No change (*From an individual at least five days and not older than one year of age, regardless of whether a first specimen was collected.*

~~68.~~69. No change (*"Sickle cell anemia" means a sickle cell disease in which an individual has two sickle cell genes.*

~~69.~~70. No change (*"Sickle cell disease" means a hemoglobinopathy characterized by an abnormally shaped red blood cell resulting from the abnormal structure of the protein hemoglobin.*

~~70.~~71. No change (*"Sickle cell gene" means a unit of inheritance that is involved in producing an abnormal type of the protein hemoglobin, in which the amino acid valine is substituted for the amino acid glutamic acid at a specific location in the hemoglobin.*

~~71.~~72. No change (*"Specimen" means a blood sample obtained from and demographic information about a newborn or infant.*

~~72.~~73. No change (*"Specimen collection kit" means a strip of filter paper for collecting a blood sample attached to a form for obtaining the information specified in R9-13-203(A)(3) about a newborn or infant.*

~~73.~~74. No change (*"Test" means a laboratory analysis performed on body fluid, tissue, or excretion to determine the presence or absence of a disorder.*

~~74.~~75. No change (*"Transfer" means a health care facility discharging a newborn and sending the newborn to a hospital for inpatient medical services without the intent that the patient will be returned to the sending health care facility.*

~~75.~~76. No change (*"Transfusion" means the infusion of blood or blood products into the body of an individual.*

~~76.~~77. No change (*"Trifunctional protein deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 12 to 18 carbon atoms in length due to defective mitochondrial trifunctional protein activity.*

~~77.~~78. No change (*"Tyrosinemia type I" means a congenital disorder characterized by an accumulation of the amino acid tyrosine due to defective fumarylacetoacetate hydrolase activity.*

~~78.~~79. No change (*"Verify" means to confirm by obtaining information through a source such as the newborn screening program, a health care provider, a health care facility, or a documented record.*

~~79.~~80. No change (*"Very long-chain acyl-CoA dehydrogenase deficiency" means a congenital disorder characterized by an inability to metabolize fatty acids that are 14 to 18 carbon atoms in length due to defective very long-chain acyl-CoA dehydrogenase activity.*

~~80.~~81. No change (*"Working day" means 8:00 a.m. through 5:00 p.m. Monday through Friday, excluding state holidays.*

R9-13-202. Tests for Congenital Disorders

A. A bloodspot test on a first specimen shall include laboratory analyses for the following congenital disorders:

1. No change (*Argininosuccinic acidemia,*

~~2.~~ ~~Biotinidase deficiency,~~

~~3.~~2. No change (*Citrullinemia,*

~~4.~~ ~~Classic galactosemia,~~

~~5.~~3. No change (*Congenital adrenal hyperplasia,*

~~6.~~4. No change (*Congenital hypothyroidism,*

~~7.~~ ~~Hemoglobin S/Beta-thalassemia,~~

~~8.~~ ~~Hemoglobin S/C disease,~~

~~9.~~5. No change (*Homocystinuria,*

~~10.~~6. No change (*Maple syrup urine disease,*

~~11.~~7. No change (*Phenylketonuria,*

~~12.~~ ~~Sickle cell anemia,~~

~~13.~~8. No change (*Tyrosinemia type I,*

~~14.~~9. No change (*3-Methylcrotonyl-CoA carboxylase deficiency,*

~~15.~~10. No change (*3-Hydroxy-3-methylglutaric aciduria,*

~~16.~~11. No change (*Beta-ketothiolase deficiency,*

~~17.~~12. No change (*Carnitine uptake defect,*

~~18.~~13. No change (*Glutaric acidemia type I,*

~~19.~~14. No change (*Isovaleric acidemia,*

~~20.~~15. No change (*Long-chain 3-hydroxy acyl-CoA dehydrogenase deficiency,*

~~21.~~16. No change (*Medium chain acyl-CoA dehydrogenase deficiency,*

~~22.~~17. No change (*Methylmalonic acidemia (Cbl A,B),*

~~23.~~18. No change (*Methylmalonic acidemia (mutase deficiency),*

~~24.~~19. No change (*Multiple carboxylase deficiency,*

~~25.~~20. No change (*Propionic acidemia,*

~~26.~~21. No change (*Trifunctional protein deficiency,*

~~27.~~22. Very long-chain acyl-CoA dehydrogenase deficiency, ~~and~~

23. Biotinidase deficiency,

24. Classic galactosemia,

~~28.~~25. Cystic fibrosis,

26. Hemoglobin S/Beta-thalassemia,

27. Hemoglobin S/C disease, and

28. Sickle cell anemia.

B. Except as specified in subsection (C), the bloodspot test on the second specimen for the individual shall include laboratory analysis for the congenital disorders listed in subsection (A).

C. If the Department verifies that a bloodspot test on a first specimen for an individual included laboratory analyses for the congenital disorders listed in subsection (A), the Department may exclude from the bloodspot test on the second specimen for the individual laboratory analysis for the congenital disorders listed in subsections (A)(23) through (A)(28).

R9-13-203. General Requirements for Newborn and Infant Bloodspot Tests

A. No change (*When a bloodspot test is ordered for a newborn or an infant, a health care facility's designee, a health care provider, or the health care provider's designee shall:*

1. No change (*Only use a specimen collection kit supplied by the Department;*
2. No change (*Collect a blood sample from the newborn or infant on a specimen collection kit;*
3. No change (*Complete the following information on the specimen collection kit:*
   a. No change (*The newborn's or infant's name, gender, race, ethnicity, medical record number, and if applicable, AHCCCS identification number;*
   b. No change (*The newborn's or infant's type of food or food source;*
   c. No change (*Whether the newborn or infant is from a single or multiple birth;*
   d. No change (*If the newborn or infant is from a multiple birth, the birth order of the newborn or infant;*
   e. No change (*Whether the newborn or infant has a medical condition that may affect the bloodspot test results;*
   f. Whether the newborn or infant received ~~antibiotics or~~ a blood transfusion and, if applicable, the date of the last blood transfusion;
   g. No change (*The method of blood sample collection;*
   h. No change (*The date and time of birth, and the newborn's or infant's weight at birth;*
   i. No change (*The date and time of blood sample collection, and the newborn's or infant's weight when the blood sample is collected;*
   j. The ~~name and~~ identification code or the name and address of the health care facility or health care provider submitting the specimen collection kit;
   k. The name, ~~identification code, and~~ address, and telephone number or the identification code of the health care provider responsible for the management of medical services provided to the newborn or infant;
   l. Except as provided in subsection (A)(3)(m), the mother's first and last names, date of birth, name before first marriage, mailing address, ~~phone~~ telephone number, and if applicable, AHCCCS identification number; and

m. If the newborn's or infant's mother does not have physical custody of the newborn or infant, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn or infant; and

4. No change (*Submit the specimen collection kit to the screening laboratory no later than 24 hours or the next working day after the blood sample is collected.*

B. No change (*A health care facility or a health care provider submitting a first specimen to the screening laboratory shall pay the Department the fee in R9-13-208(A).*

C. No change (*A person who submits a second specimen to the screening laboratory shall:*

1. No change (*Pay the fee in R9-13-208(B) to the Department, or*
2. No change (*Provide the following information to the screening laboratory for billing purposes:*
   a. The name, mailing address, and ~~phone~~ telephone number of the newborn's or infant's parent or the individual responsible for paying, if not the parent; and
   b. No change (*If the individual responsible for paying has health care insurance for the newborn or infant, information about the health care insurance, including:*
      i. No change (*The policyholder's name;*
      ii. No change (*The name and billing address of the health care insurance company;*
      iii. No change (*The member identification number;*
      iv. No change (*The group number, if applicable; and*
      v. No change (*The effective date of the health care insurance; or*
   c. No change (*That the individual responsible for paying has no health care insurance for the newborn or infant.*

D. No change (*When a health care insurance company or an individual responsible for paying is identified as specified in subsection (C)(2), the health care insurance company or the individual responsible for paying shall pay the Department the fee in R9-13-208(B).*

E. No change (*The screening laboratory shall perform a bloodspot test on a blood sample from a specimen collection kit if:*

1. No change (*The blood sample on the specimen collection kit:*
   a. No change (*Contains a sufficient quantity of blood to complete the bloodspot test,*
   b. No change (*Is not clotted or layered,*
   c. No change (*Does not have serum rings,*
   ~~d. Is not diluted or discolored,~~
   ~~e.~~d. No change (*Will elute from the filter paper,*
   ~~f.~~e. No change (*Has not been applied to both sides of the filter paper, and*

~~g.~~f. No change (*Is not contaminated;*

~~2. The filter paper on the specimen collection kit is not contaminated, scratched, or abraded;~~

~~3. The information on the specimen collection kit is sufficient to identify:~~

~~a. The newborn or infant, and~~

~~b. The person who ordered the bloodspot test or caused the bloodspot test to be ordered; and~~

2. The filter paper on the specimen collection kit:

a. Is not contaminated, scratched, or abraded; and

b. Does not contain a date before the date of blood sample collection;

3. The information on the specimen collection kit is sufficient to:

a. Identify:

i. The newborn or infant, and

ii. The person who ordered the bloodspot test; and

b. Allow accurate testing and reporting of results;

4. The screening laboratory receives the specimen collection kit within 14 days after the blood sample ~~is~~ was collected; and

5. The results of the laboratory analyses for the congenital disorders specified in R9-13-202(A) meet quality standards adopted by the screening laboratory in compliance with 42 CFR 493.1200.

F. No change (*When a home birth not attended by a health care provider is reported to a local registrar, a deputy local registrar, or the state registrar under A.R.S. § 36-333:*

1. No change (*The local registrar, deputy local registrar, or state registrar shall notify the local health department of the county where the birth occurred; and*

2. No change (*The local health department's designee shall collect a specimen from the newborn or infant according to the requirements in R9-13-204(A)(2) or R9-13-205(C).*

G. No change (*A health care facility's designee, a health care provider, or the health care provider's designee shall ensure that:*

1. No change (*Educational materials are provided to the parent or guardian of a newborn or infant for whom a bloodspot test is ordered, and*

2. No change (*The newborn's or infant's parent or guardian is informed of the requirement for a second specimen if the second specimen has not been collected.*

H. No change (*For a home birth, a health care provider or the health care provider's designee shall provide educational materials to the parent or guardian of a newborn or infant for whom a bloodspot test is ordered.*

R9-13-204. First Specimen Collection

A. No change (*When a newborn is born in a hospital, the hospital's designee shall collect a first specimen from the newborn according to whichever of the following occurs first:*

1. No change (*Before a transfusion, unless specified otherwise by a physician, physician assistant, or registered nurse practitioner;*
2. No change (*When the newborn is at least 24 but not more than 72 hours old; or*
3. No change (*Before the newborn is discharged, unless the newborn:*
   a. *No change (Is transferred to another hospital before the newborn is 48 hours old; or*
   b. No change(*Dies before the newborn is 72 hours old.*

B. No change (*If a newborn is admitted or transferred to a hospital before the newborn is 48 hours old, the receiving hospital's designee shall:*

1. No change (*Verify that the first specimen was collected before admission or transfer, or*
2. No change (*Collect a first specimen from the newborn according to the requirements in subsection (A).*

C. No change (*When a newborn is born in a birth center, the birth center's designee shall collect a first specimen from the newborn according to subsections (A)(1) or (A)(2).*

D. No change (*For a home birth attended by a health care provider, the health care provider or the health care provider's designee shall collect a first specimen from the newborn according the requirements in subsection (A)(2).*

R9-13-205. Second Specimen Collection

A. No change (*After discharge from a health care facility or after a home birth, a health care provider or the health care provider's designee shall:*

1. No change (*Collect a second specimen from a newborn or infant:*
   a. When the newborn is at least ~~5~~ five but not more than 10 days old; or
   b. No change (*At the time of a newborn's or infant's first visit to the health care provider; or*
2. No change (*Verify that a different health care provider has collected the second specimen from the newborn or infant.*

B. If a newborn is an inpatient of a health care facility at ~~5~~ five days of age, the health care facility's designee shall collect a second specimen from the newborn:

1. When the newborn is at least ~~5~~ five but not more than 10 days old; or
2. If the newborn is discharged from the facility when the newborn is at least ~~5~~ five but not more than 10 days old, before discharge.

C. No change (*For a home birth not attended by a health care provider, a local health department's designee shall collect a specimen from a newborn or infant if a second specimen has not already been collected from the newborn or infant.*

D. No change (*A health care provider or the health care provider's designee shall ensure that a subsequent specimen is ordered for a newborn or child one year of age or less, according to the requirements in R9-13-203, when the health care provider or the health care provider's designee:*

1. No change (*Begins providing health care to the newborn or child, and*
2. No change (*Cannot verify the results of a bloodspot test that was conducted on a second specimen from the newborn or child.*

R9-13-206. Reporting Requirements for Specimens

A. No change (*The screening laboratory shall:*

1. No change (*Report in written or electronic format:*
   a. No change (*The results of a bloodspot test on a specimen; and*
   b. No change (*For a specimen that does not meet the requirements for testing specified in R9-13-203(E):*
      i. No change (*That the bloodspot test was not performed on the specimen; and*
      ii. No change (*The reason the bloodspot test was not performed; and*
2. No change (*Send the report to:*
   a. The health care provider identified on the specimen collection kit; and
   b. If applicable, the health care facility identified on the specimen collection kit~~;~~ ~~and~~.
   ~~c. The Department.~~

~~**B.** The screening laboratory shall begin reporting bloodspot test results for the congenital disorders specified in:~~

~~1. R9-13-202 (1) through (13), on the effective date of these rules;~~

~~2. R9-13-202(14) through (27), no later than August 31, 2006; and~~

~~3. R9-13-202(28), no later than June 30, 2007.~~

~~**C.**~~**B.** No change (*A health care facility's designee, a health care provider, or the health care provider's designee, who orders a subsequent test on a newborn or infant in response to an abnormal result on a bloodspot test, shall send the results of the subsequent test in writing to the Department, if the subsequent test is not performed by the screening laboratory.*

~~**D.**~~**C.** No change (*Bloodspot test results are confidential subject to the disclosure provisions of 9 A.A.C. 1, Article 3, and A.R.S. §§ 12-2801 and 12-2802.*

R9-13-207. Reporting Requirements for Hearing Test Results

A. No change (*When an initial hearing test is performed on a newborn, a health care facility's designee, a health care provider, or the health care provider's designee shall provide to the Department, as specified in subsection (E), the following information:*

1. No change (*The newborn's name, date of birth, gender, and medical record number;*
2. No change (*Whether the newborn is from a single or multiple birth;*
3. No change (*If the newborn is from a multiple birth, the birth order of the newborn;*
4. The ~~newborn's mother's~~ first and last names and date of birth of the newborn's mother;
5. ~~The name and identification code of the health care facility or the health care provider submitting the hearing test results;~~
6. ~~6.~~5. The name and identification code of the health care facility of birth;
6. The name and identification code of the health care facility where the initial hearing test was performed, if different from the health care facility of birth, or the name and telephone number of the health care provider who performed the initial hearing test;
7. No change (*The name of the health care provider responsible for the coordination of medical services for the newborn;*
8. No change (*The date of the hearing test;*
9. No change (*Whether or not the hearing test was performed when the newborn was an inpatient;*
10. No change (*The audiological equipment used for the hearing test and the type of hearing test performed;*
11. No change (*The hearing test result for each of the newborn's ears; and*
12. The name, address, and ~~phone~~ telephone number of the contact person for the health care facility or health care provider.

B. No change (*In addition to the information in subsection (A), if the reported results of an initial hearing test on a newborn include an abnormal result, a health care facility's designee, a health care provider, or the health care provider's designee shall provide to the Department, as specified in subsection (E), the following information:*

1. The newborn's race~~,~~ and ethnicity~~, and if applicable, AHCCCS identification number~~;
2. Except as provided in subsection (B)(3), the mother's ~~date of birth,~~ name before first marriage, mailing address, and ~~phone~~ telephone number;
3. If the newborn's mother does not have physical custody of the newborn, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn;

4. The name of the health care provider who will be responsible for the coordination of medical services for the newborn after the newborn is discharged from the health care facility, if different from the individual specified in subsection (A)(7); and
5. The name and ~~phone~~ telephone number of the person to whom the newborn's mother or other person who has physical custody of the newborn was referred for a subsequent hearing test.

C. No change (*When a hearing test is performed on a newborn or an infant after an initial hearing test, the designee of the health care facility, health care provider, or other person that performs the subsequent hearing test shall provide to the Department, as specified in subsection (E), the following information:*

1. No change (*The newborn's or infant's name, date of birth, and gender;*
2. No change (*Whether the newborn or infant is from a single or multiple birth;*
3. No change (*If the newborn or infant is from a multiple birth, the birth order of the newborn or infant;*
4. The ~~newborn's mother's~~ first and last names and date of birth of the newborn's mother;
5. The name of the health care facility of birth;
~~5.~~6. The name of the health care facility where the initial hearing test was performed, if different from the health care facility of birth, or the name and ~~address~~ telephone number of the health care provider who performed the initial hearing test;
~~6. The name of the health care facility of birth;~~
7. The name, telephone number, and identification code of the person submitting the subsequent hearing test results;
8. No change (*The date of the subsequent hearing test;*
9. The ~~audiological equipment used for the subsequent hearing test and the~~ type of hearing test performed;
10. The result, including quantitative results if applicable, for each of the newborn's or infant's ears on the subsequent hearing test; and
11. The name~~, address,~~ and ~~phone~~ telephone number of the contact person for the health care facility, health care provider, or other person that performed the subsequent hearing test, if different from the person specified in subsection (C)(7).

D. In addition to the information in subsection (C), if the reported results of a subsequent hearing test on a newborn or infant include an abnormal result, the person submitting the report on the subsequent hearing test shall provide to the Department, as specified in subsection (E), the following ~~information~~:

1. Except as provided in subsection (D)(2), the ~~newborn's or infant's mother's mailing address and phone number~~ mailing address and telephone number of the newborn's or infant's mother;
2. If the newborn's or infant's mother does not have physical custody of the newborn or infant, the first and last names, mailing address, and ~~phone~~ telephone number of the person who has physical custody of the newborn or infant;
3. The name of the health care provider who is responsible for the coordination of medical services for the newborn or infant; ~~and~~
4. If applicable, the name and ~~phone~~ telephone number of the person to whom the newborn's or infant's parent was referred for further hearing tests, evaluation services, specialty care, or early intervention~~.~~;
5. The audiological equipment used for the subsequent hearing test; and
6. If a diagnostic hearing test was performed on the newborn or infant:
   a. Whether the newborn or infant has a hearing loss and, if so, the type and degree of hearing loss; and
   b. A copy of the narrative that describes the diagnostic hearing tests performed on the newborn or infant, the results of each diagnostic hearing test, and the analysis of the diagnostic hearing test results by the audiologist or physician who performed the diagnostic hearing tests.

E. No change (*A health care facility's designee, health care provider, health care provider's designee, or other person required to report under subsections (A), (B), (C), or (D) shall submit, in an electronic format specified by the Department, the information specified in subsections (A), (B), (C), or (D) for hearing tests performed each week by the sixth day of the subsequent week.*

R9-13-208. Fees

A. No change (*The fee for a first specimen is $30.00.*

B. No change (*The fee for a second specimen is $40.00.*